Dr. Farhan Khan
Chief Executive Officer

MEDLINK WORLD LLC
(Clinical Validators of several Covid 19 Tests)

Medlink World LLC is headquartered in New York City and has been engaged in the healthcare field for the past 18 years, having made significant impact in the epidemic and pandemic of infectious disease. Its primary goal is to assist local and international entities in disease containment by launching a robust screening program.

Dr. Farhan Khan

Medlink World LLC

Chief Executive Officer

Dr Khan is a leading healthcare consultant with strong analytical skills and healthcare business process knowledge combined with Public Health expertise. Dr. Khan with his leadership and team building spirit heads Medlink, headquartered in New York, and actively operating in UK and UAE.

He is a seasoned and successful healthcare expert who has contributed significantly to the public health space, right from the days of first outbreak of SARS, and MERS since 2013, with focus on clinical diagnostic modality and large scale infectious disease screening programs.

Dr. Khan was the first and only American doctor quarantined in Seoul-South Korea in 2014 when travelling on an invitation from Korean FDA..

Dr Khan with his 18 years of experience in Healthcare diagnostics and subject matter expertise in molecular and AI assisted diagnostics is keenly focused on market needs and practical scalable solutions to public health needs, in the event of a pandemic. Stellar career history in Public Health, Molecular biology, Infectious disease validation and screening program.

CareStart Covid Antigen Test (FDA-EUA)

Approved for POC (CLIA Waived)

Background :

Due to the highly contagious nature and global health crisis, SARS-CoV-2 has been designated as a pandemic by the World Health Organization (WHO) and continues to have devastating impacts on healthcare systems and the world economy including the U.S. To effectively end the SARS- CoV-2 pandemic, systematic screening and detection of both clinical and asymptomatic COVID-19 cases is critical.

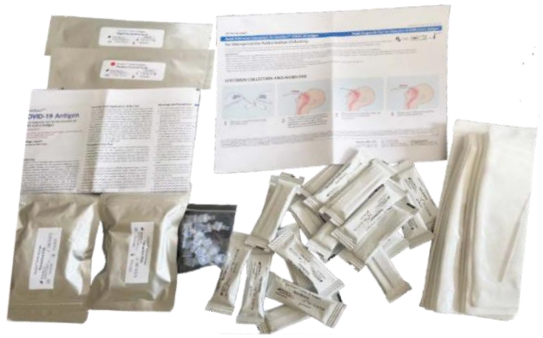
Solution :

As an intended point-of-care (POC) designated test with a 10 minutes processing time, CareStart™ COVID-19 Antigen Test allows effective screening of COVID-19 infection on a large scale.

Unique Features of the Diagnostic Solution.

- No Instrumentation required (Visually read by naked eyes)
- Lateral flow assay
- Rapid results in 10 minutes
- Specimen used is nasopharyngeal swab
- Intended use at POC setting (i.e., in patient care settings) by Healthcare Staff
- Detect SARS-CoV-2 nucleocapsid protein antigen
- Identify acute infection with high sensitivity of 88.7% and 100% specificity.

1 Covid Antigen test kit contains 20 tests in a Box



Inner Contents of the Box

- Medlink World LLC has access to large product lots for immediate delivery of CareStart antigen Test.
- With COVID-19 Antigen Rapid Point of Care test kits you get results in ten minutes. For use by healthcare professionals in CLIA waived settings. Very affordable. No separate analyzer or equipment needed. Authorized by the FDA for emergency use.
- This Antigen tests provide an important service to patients, essential workers, government agencies, educators pharmacy and others who need information relating to their exposure to infection of COVID-19.
- With the second wave of COVID-19 infections underway, the demand for antigen testing solutions has never been higher. The CareStart test kit supplied by Medlink World can be an important tool in the service of the community.

COVID-19 ANTIGEN RAPID TESTS

PRODUCT HIGHLIGHTS

Test	Carestart Antigen
Technique	Lateral flow chromatographic Immunoassay
Instrument Required	No
Preparation Time	None
Known Cross Reactivity	No
Processing time	1O minutes
Clinical Sensitivity	88.7%%
Clinical Specificity	100%
Specimen Type	Nasopharyngeal
Analytical Sensitivity (LOO)	$8x10^2$ $TCID_{50}$/mL [a]
Point-of-Care	Yes
Target	Nucleocapsid antigen
FDA Authorization	Yes

a*-This LOD is when the swab was used with VTM and not CareStart extraction buffer. With CareStart extraction buffer LOD is 1.2X 10^2 $TCID_{50}$/mL

FDA Authorization Letter

U.S. FOOD & DRUG ADMINISTRATION

October 8, 2020

San Joon Han
Associate Principal Scientist / R&D Division
Access Bio, Inc.
65 Clyde Road Suite A
Somerset, NJ 08873

Device:	*CareStart* COVID-19 Antigen test
Company:	Access Bio, Inc.
Indication:	Qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab specimens directly collected, or collected in BD universal transport media, from individuals suspected of COVID-19 by their healthcare provider within five days of symptom onset. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Dear San Joon Han:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Access Bio, Inc..
[2] For ease of reference, this letter will use the term "your product" to refer to the *CareStart* COVID-19 Antigen test used for the indication identified above.

For Emergency Use Authorization (EUA) Only

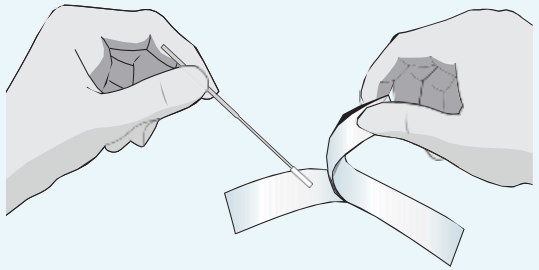
The *CareStart*™ COVID-19 Antigen test is a lateral flow immunochromatographic assay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab specimens directly collected from individuals who are suspected of COVID-19 by their healthcare provider within ve days of symptom onset.

Only Rx IVD 1°C 30°C

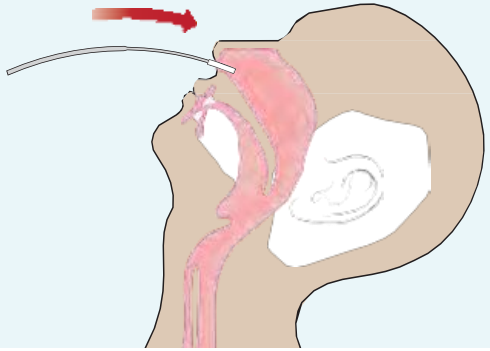
IMPORTANT

-Refer to the Package Insert for Warnings and Precautions, Specimen Collection Procedures, Storage and Handling Conditions, and Quality Control Recommendations.
-Warning and Precautions - All kit components can be discarded as Biohazard waste according to local guidelines. Refer to the product safety data sheet for risk and safety phrases and disposal information.
-Biotin Interference: False negative results may occur in patients who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin (> 10 mg per day). Biotin levels of 2.5 µg/mL have been demonstrated to result in false negative test results.
-The extracted sample must be used within 4 hours of preparation when stored at room temperature.
-Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

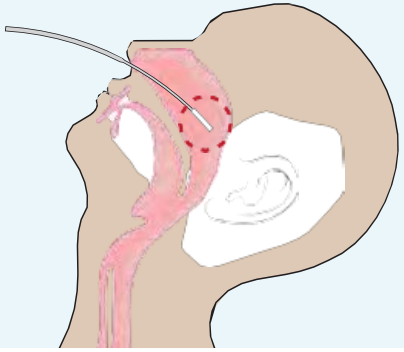
SPECIMEN COLLECTION AND HANDLING



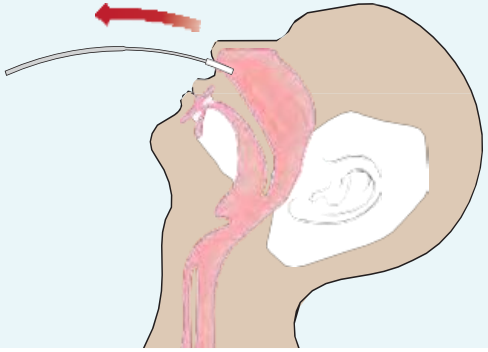
Remove from the pouch a nasopharyngeal swab



Place the swab into one of patient's nostrils until it reaches the posterior nasopharynx; keep insert until resistance is equivalent to that from the ear to the nostril of the patient.



Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx.



Slowly remove the swab from the nostril while rotating it.

The USP of CareStart Antigen kit

- **The Carestart antigen test kit outstanding specificity makes it a fit tests for large scale screening program.**

- **All positive cases need to be confirmed with a PCR. Negative test results need not go for RT-PCR tests because the test has 100% specificity***

* All diagnosis should be made keeping in mind corroborating patient evidence, symptoms and exposure to COVID-19. No diagnosis should be made on single evidence or in isolation.

References

Our Current Clients

- Private Clinics
- Urgent Care Clinics
- Airlines (KLM, Alitalia, Lufthansa, Air Moroc, Air France, Turkish Airlines)
- Jacobi Hospital
- NJ Spine and Surgery Chain
- Orthopedic Chain
- Port Authority of NY/NJ, Customs and Border Security force

CREATING A SAFER WORLD

Contact: info@medlinkworld.com
Tel: 1-718-428-2560
Fax: 1-678-868-4807
Address: 147W, 35th St,
New York, NY 10001

Robust solution to Combat the pandemic of COVID 19